REMARKS

Introduction

Applicants have amended claim 1 to recite further aspects of the invention, as described, for example, in page 5, line 5 to 9.

Priority

Applicants have added a specific reference to the prior application from which priority is claimed, in the first line of the specification.

Claim Objections

Claims 16 – 18 have been amended to remove the term "evacuated blood collection" which lacked proper antecedent basis. Claim 17, line 4 has also been amended to remove "said" to give "a planar surface on said laboratory apparatus."

Claim Rejections- 35 USC§ 102

Claims 14, 16 and 17 were rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 3,656,473 to Sodickson et al. ("Sodickson"). The rejection is respectfully traversed as to the amended claims.

Claim 14 recites a method of achieving accurate machine reading on a tube. This process involves the use of a tube, which is made with an alignment key, which has an array of information imparted onto the cylindrical side wall of the tube by a first piece of apparatus prior to any sample collection. The tube is then used to collect a sample of biological fluid after which the tube is positioned in a laboratory apparatus distinct from said first apparatus such that said alignment key engages an alignment structure on said laboratory apparatus, thereby allowing said laboratory apparatus to read said information on said tube from a specified angular position relative to said alignment key.

In the office action the Examiner states that all the elements of original Claim 14 are disclosed in Sodickson. However applicants note that the elements of Sodickson's method are dissimilar and in a different order when compared to the elements of amended Claim 14. Sodickson states that a specimen from the patient is drawn into a specimen container having a

blank label area, after which the tube is inserted into the apparatus where the label is impressed with the encoded patient identification data. The encoded label is then scanned immediately after the impressing step, still using the same apparatus to check for errors in the patient identification data.

In contrast to the claimed invention, the specimen container in Sodickson already contains the specimen when the label is encoded. This is a significant difference between the two methods. For example, the label (hence specimen) in the Sodickson method is exposed to elevated temperatures in order to impress the patient identification data (column 2, lines 70 to 75), which in turn may have an adverse effect on the patient's specimen, thereby affecting subsequent test results. Similarly such action might impact mixing, timing or other preanalytical variables. Such issues are not present in the applicant's invention, due to the impartation of information array to the tube occurring before the specimen of biological fluid is obtained.

Sodickson also discloses a single piece of apparatus (Figure 2) A Portable Label Encoder, in which the patient identification data is impressed onto the specimen container label and then immediately verified by a scanner. Applicant's invention involves a first apparatus for providing the array of information and a distinct second apparatus, e.g. a code reader located in analytical equipment, in which the alignment key ensures that the code reader can read the array of information on the tube.

Therefore Sodickson does not recite each element of applicant's claimed method. For these reasons, applicants submit that Claim 14, as amended, and its dependent claims are not anticipated by the cited reference.

Claim Rejections- 35 USC§ 103

Claim 15 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Sodickson et al. as applied to Claim 14 above and further in view of U.S. Patent No. 3,350,946 to Isreeli ("Isreeli").

Sodickson does not render Claim 14 as obvious. As discussed above Sodickson states that the specimen container must be impressed by the encoded patient identification data after the specimen has been placed in the container. This teaches away from Applicant's claimed method, which mandates that a tube must contain data before the specimen is collected. The patient and tube aren't correlated until after the specimen collection.

Sodickson also claims single piece of apparatus (Figure 2) A Portable Label Encoder. This also teaches away from Applicant's claimed method, which recites two separate pieces of equipment, i.e. an encoder and a code reader.

Isreeli does not remedy the shortcomings of Sodickson. Isreeli is relied on only for its showing of an substantially planar fin (alignment key) lying in a plane passing through the longitudinal axis of the tube, the method comprising of engaging said fin in a slot formed in the laboratory apparatus.

Claims 18-20 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Sodickson et al. as applied to Claim 14 above and further in view of U.S. Patent No. 5,670,117 to Erb et al. ("Erb").

Sodickson does not render Claims 18-20 as obvious, for exactly the same reasons as stated previously on page 6.

Erb does not remedy the shortcomings of Sodickson. Erb is relied on only for its showing that one-dimensional bar codes, two-dimensional bar codes, magnetic strips and printed alphanumeric symbols can be used as identification marks to identify a tube.

In view of the amendments and remarks above, applicants respectfully request reconsideration of the application, and allowance of all claims.

If there are any additional fees related to this Amendment, such fees should be charged to Deposit Account No. 02-1666.

Respectfully submitted,

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